K061223 (pg 1 of 2)

AUG 18 2006

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the ADVANCE® Total Knee System.

Submitted By:	Wright Medical Technology, Inc.
Date:	May 1, 2006
Contact Person:	Theresa Leister Regulatory Affairs Specialist II
Proprietary Name:	ADVANCE® Total Knee System
Common Name:	KNEE SYSTEM
Classification Name and Reference:	21 CFR 888.3565 Knee joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis – Class II
Device Product Code and Panel Code:	Orthopedics/87/ MBH

DEVICE INFORMATION

A. INTENDED USE

The ADVANCE® Total Knee System is indicated for use in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with the following conditions:

1) noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
2) inflammatory degenerative joint disease including rheumatoid arthritis;
3) correction of functional deformity;
4) revision procedures where other treatments or devices have failed; and
5) treatment of fractures that are unmanageable using other techniques.

The ADVANCE® Total Knee System components are for use without bone cement and are single use devices.

K061223 (pg 2 of 2)

B. DEVICE DESCRIPTION

The ADVANCE® Total Knee System contains femoral components, tibial components, and modular keel components. The ADVANCE® Total Knee System components are compatible with existing ADVANCE® tibial inserts and patellas. The design features and function of the ADVANCE® Total Knee System components are substantially equivalent to the design features and function of devices previously cleared under the ADVANCE® Total Knee System and are highlighted below.

- Manufactured from Cobalt Chrome Alloy or Titanium Alloy
- Manufactured with porous coating
- Accessory components available without porous coating
- Available with or without HA coating
- Intended for use without bone cement

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, material, type of interface, and design features of ADVANCE® Total Knee System are substantially equivalent to the currently available ADVANCE® Total Knee System implants. The safety and effectiveness of ADVANCE® Total Knee System are adequately supported by the substantial equivalence information, materials data, and testing results provided within the Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 18 2006

Wright Medical Technology, Inc.
c/o Ms. Theresa Leister
Regulatory Affairs Specialist II
5677 Airline Road
Arlington, Tennessee 38002

Re: K061223
Trade/Device Name: ADVANCE® Total Knee System
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: MBH
Dated: July 18, 2006
Received: July 19, 2006

Dear Ms. Leister:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061223

Device Name: ADVANCE® Total Knee System

Indications For Use:

The ADVANCE® Total Knee System is indicated for use in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with the following conditions:

1) noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
2) inflammatory degenerative joint disease including rheumatoid arthritis;
3) correction of functional deformity;
4) revision procedures where other treatments or devices have failed; and
5) treatment of fractures that are unmanageable using other techniques.

The ADVANCE® Total Knee System components are for use without bone cement and are single use devices.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061223